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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,181	07/09/2001	J. Lawrence Burg	97,195-P	6516

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EXAMINER

PANARO, NICHOLAS J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/901,181

Applicant(s)

BURG ET AL

Examiner

Nicholas J. Panaro

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 10-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 10-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/7/05

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "said signal". There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s)

because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 1, 10, 14-16 and 21-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,300,068.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 10 of the instant application are generic to all that is recited in claim 1 of U.S. Patent No. 6,300,068. That is, claim 1 of U.S. Patent No. 6,300,068 falls entirely within the scope of claims 1 and 10 of the instant application or, in other words, claims 1 and 10 of the instant application are anticipated by claim 1 of U.S. Patent No. 6,300,068.

Claim 1 of U.S. Patent 6,300,068 teaches similar steps to those taught by claims 1 and 10 of the instant application. Regarding claim 10 of the instant application, claim 1 of U.S. Patent 6,300,068 comprises the additional limitations of contacting the amplicon with a capture nucleic acid to form a specifically-bound nucleic acid-capture probe complex, optionally washing said specifically-bound nucleic acid-capture probe complex such that non-specifically-bound nucleic acid is washed away, contacting said specifically-bound nucleic acid-capture probe complex with a labeled nucleic acid probe such that a specifically-bound nucleic acid-capture probe-labeled probe complex can form, optionally washing said specifically-bound nucleic acid-capture probe-labeled probe complex such that non-specifically-bound probe is washed away, and optionally displaying a value for a signal, optionally recording the value of the signal and wherein the signal is proportional to the amount of amplicon in the sample.

Specifically, claim 10(a) of the instant application is taught by claim 1(a) of U.S. Patent No. 6,300,068 (column 25, lines 32-37); claim 10(b) of the instant application is taught by claim 1(b) of U.S. Patent No. 6,300,068 (column 25, lines 38-45); claim 10 (c) of the instant application is taught by claim 1(c) of U.S. Patent No. 6,300,068 (column 25, lines 46-49); claim 10 (d) of the instant application is taught by claim 1(c) of U.S. Patent No. 6,300,068 (column 25, lines 50-55); claim 10 (e) of the instant application

is taught by claim 1(e) of U.S. Patent No. 6,300,068 (column 25, lines 56-60) and claim 10(f) of the instant application is taught by claim 1(j) of U.S. Patent No. 6,300,068 (column 26, lines 25-34).

Claims 11-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Burg et al (U.S. Patent No. 6,300,068) in view of Backus et al (U.S. Patent 6,280,930).

Regarding claim 11, claim 1 of U.S. Patent No. 6,300,068 recites a method for the detection of the presence or absence of a single or double stranded first nucleic acid in a sample. The method of claim 1 differs from claim 11 herein in that it fails to teach capturing amplicons with a nucleic acid capture probe bound on a solid support such that a capture probe hybridization complex is formed. Backus et al teach a method for detecting a target nucleic acid sequence with a solid phase capture probe comprising a nucleic acid sequence which hybrids to at least a portion of said amplified nucleic acid sequence, said capture probe not participating in nucleic acid amplification process (column 9, line 66 – column 10, line 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to add the teachings of Backus et al to the teachings of Burg et al.

Regarding claim 12, Backus et al teach a method for detecting a target nucleic acid sequence with a labeled solid phase capture probe (column 9, line 66 – column 10, line 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to add the teachings of Backus et al to the teachings of Burg et al.

Regarding claim 13, Backus et al teach a biotinylated capture probe (column 6, lines 23-32) to generate a detectable signal. Backus et al teach contacting said labeled probe complex (i.e., biotin-labeled probe) with a substrate (i.e., streptavidin-peroxidase conjugate) in the presence of an oxidant (i.e., hydrogen peroxide) and a dye-forming compound (tetramethylbenzidine) (column 10, lines 14-24) to generate a detectable signal whereby said signal is proportional to the amount of said first nucleic acid in

said test sample. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to add the teachings of Backus et al to the teachings of Burg et al.

Claims 11 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Burg et al (U.S. Patent No. 6,300,068) in view of Backus et al (U.S. Patent 6,280,930) in further view of Harris et al (U.S. Patent 5,849,544).

Regarding claim 17, Harris et al a pipet-like device (i.e., a dipstick) for solid phase capture of amplicons (column 2, lines 46-57). A dipstick is interpreted as falling within the broad scope of pipet-like device. The use of a dipstick may prove advantageous for the calorimetric detection of specific nucleic acid sequences by isothermal amplification (column 2, lines 57-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to add the teachings of Backus et al and Harris et al to the teachings of Burg et al.

Claims 19-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Burg et al (U.S. Patent No. 6,300,068) in view of Collins et al (U.S. Patent 6,268,128).

Regarding claim 19, Collins et al teach washing a capture probe hybridization complex bound on a solid support such that non-specifically bound amplicons and nucleic acids are washed away from said solid support (column 26, lines 18-35) for the advantage of reducing nonspecific hybridization (column 7, lines 37-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to add the teachings of Collins et al to the teachings of Burg et al.

Regarding claim 20, Collins et al teach washing a labeled capture probe hybridization complex bound on a solid support such that non-specifically bound amplicons and labeled nucleic acids are washed away from said solid support (column 26, lines 18-40) for the advantage of reducing nonspecific hybridization (column 7, lines 37-39). Therefore, it would have been obvious to one of ordinary skill in the

art at the time of the claimed invention was made to add the teachings of Collins et al to the teachings of Burg et al.

Claims 25-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Burg et al (U.S. Patent No. 6,300,068) in view of Bishop et al (U.S. Patent 5,697,409).

Regarding claim 25, Bishop et al teach a fluid transferred to a second vessel (i.e., shot tube) through a fluid channel a first vessel (i.e., conduit) said fluid channel comprising a valve (column 7, lines 52-53) wherein said valve may be a thimble valve which can be retracted to a closed position for the advantage of preventing pressure surges (column 9, lines 47-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to add the teachings of Bishop et al to the teachings of Burg et al.

Regarding claim 26, Bishop et al teach a fluid transferred to a second vessel (i.e., shot tube) through a fluid channel a first vessel (i.e., conduit) said fluid channel comprising a thimble valve (column 7, lines 52-53) wherein a thimble valve can be retracted to a closed position for the advantage of preventing pressure surges (column 9, lines 47-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to add the teachings of Bishop et al to the teachings of Burg et al.


Conclusion

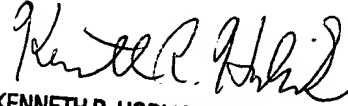
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas J. Panaro whose telephone number is (571) 272-0778. The examiner can normally be reached on Monday - Friday 7:00 am to 3:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NJP



KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

3/21/05